

REMARKS

This Amendment responds to the Office Action dated January 24, 2008 in which the Examiner rejected claims 1, 3-5 and 7-20 under 35 U.S.C. §103.

Claim 1 claims an injection needle and claim 4 claims a liquid introducing instrument comprising an injection needle. The injection needle comprises a puncture section having a needle point capable of piercing a living body, a proximal end section having outside and inside diameters greater than the puncture section, and a tapered section interconnecting the puncture section and the proximal end section. The proximal end section possesses an outside diameter ranging from 0.35 mm to 1 mm, and the puncture section possesses an outside diameter ranging from 0.1 mm to 0.5 mm. The length from the puncture section to the tapered section ranges from 0.2 mm to 15 mm. The tapered section possesses an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle. In addition, the tapered section provides puncture resistance smaller than the puncture section.

To better define aspects of the injection needle and the liquid introducing instrument in a manner that further distinguish over the disclosures in the cited references, Claims 1 and 4 are amended to recite that the total length of the puncture section, the proximal end section and the tapered section ranges from 5 mm - 40 mm.

Claims 1, 3, 4, 5, 19 and 20 were rejected under 35 U.S.C. §103 as being unpatentable over Gross (U.S. Patent. 4,781,691). Applicants note that claims 19 and 20 have previously been cancelled. This rejection is respectfully traversed.

As explained previously, Gross discloses a needle assembly for performing a spinal anesthesia procedure whereas the needle and liquid introducing instrument of claims 1 and 4 respectively, may be used for performing hypodermic and intramuscular administration. The needle assembly of Gross includes a needle 10 having a hollow proximal hub 12, a first tubular portion 14 of uniform diameter extending distally from and connected to the hub 12, and tubular end portion 16 located distal of the first tubular portion 14 and having a smaller uniform diameter than the first tubular portion 14. In addition, a tapered intermediate portion 18 is positioned between the first tubular portion 14 and the second tubular portion 16.

In a spinal anesthesia procedure, the second tubular portion 16 of the needle assembly of Gross is used to puncture only a particular portion of body tissue, such as the ligamentum flavum. Thus, as disclosed in Gross at the top of column 4, the length of the first tubular portion 14, the intermediate portion 18, and the second tubular portion 16 may be approximately three and a half inches or approximately 8.9 cm.

The present application describes why it is desirable to configure a needle so that the total length of the puncture section, the proximal end section and the tapered section ranges from 5 mm to 40 mm. Generally, for hypodermic and intramuscular administration, the injection needle is inserted into a living body at a depth ranging from 5 mm to 40 mm, and the length is selected depending on the location and the purpose. Therefore, the upper limit for the length, for example, from the puncture section to the tapered section should desirably be set from the standpoint of maintaining a predetermined mechanical strength and reducing an increase in flow passage resistance encountered when the liquid medication is injected. The lower

limit should take into consideration piercing a living body as is necessary to achieve a desired result. If a needle having a small diameter puncture section is used to pierce a living body, it is difficult for an injection needle to maintain the required mechanical strength. It also may be difficult for only a small diameter puncture section to provide a length required in view of injection resistance because a section with a small inside diameter would have to be relatively long. Consequently, an injection needle according to the invention has a tapered section which also pierces a living body to thus obtain the required mechanical strength as well as controlling flow passage resistance.

One point that is apparent is that Gross is not concerned about the length of the first tubular portion 14 and the intermediate tubular portion 18. The dimension of the second tubular portion is given as 0.25" to 0.75" and the overall length of the three portions is given as 3" to 5" (8.9 cm).

As shown in FIGS. 2 and 3 of Gross, the disclosed needle assembly also includes a stylet 22 in the form of an elongated rod. The rod 24 is positioned inside the needle 10 and extends through the hub 12, the first tubular portion 14, the intermediate portion 18, and the second tubular portion 16 of the needle 10. The stylet 22 has a beveled tip 26 which is flush with the beveled tip 20 of the needle 10. As shown in FIG. 9, the rod 24 is configured with an enlarged first portion 60 possessing an outer diameter approximately equal to the inner diameter of the first needle portion 14, and a smaller distal portion 62 possessing an outer diameter approximately equal to the inner diameter of the second needle portion 16. Gross states in column 4, lines 9-26 that the stylet 22 is needed to provide additional strength to the needle 10 during use.

This stylet 22 is a necessary part of the overall needle assembly because, as Gross notes, the stylet imparts necessary strength to the needle 10, a requirement as the needle is advanced through the dura mater and into the subarachnoid space below the spinal cord. Because Gross provides the stylet, there is no concern with setting the length to provide mechanical strength while reducing an increase in flow passage resistance.

For at least the foregoing reasons, withdrawal of the rejection of independent Claims 1 and 4 is respectfully requested.

The dependent claims are allowable at least by virtue of their dependence upon allowable independent Claims 1 and 4. Thus, a discussion of the additional distinguishing features recited in the dependent claims is not set forth at this time.

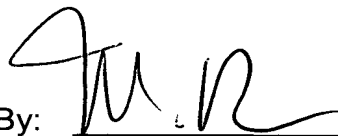
Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: April 24, 2008

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